CHAPTER OVERVIEW:

This chapter outlines the Children's Division policies and procedures on research protections and requests for release of data.

3.1 Research Protections and Request for Release of Data

The Department of Social Services' (DSS) Children's Division (CD) permits research and release of data involving persons served. In doing so, however, the Division exhibits due regard for the study subjects' participation rights with emphasis in areas of privacy and confidentiality. All research and release of data involving persons served is conducted in accordance with applicable legal requirements.

3.1.1 Request to Conduct Research Procedures

a. The entity requesting to do research must complete an Application to Conduct Research/Study form (http://dssweb/dpl/adman/POLICIES/5-103ex9.pdf). Related information must accompany the application including:

- Written positions of any Institutional Review Boards (IRBs) that may have reviewed the study proposal.

- Copies of any proposed informed consent forms which are subject to approval of the CD. Each research project is unique in at least some aspect and the form should be customized to each project. Consent forms must address the following: Youth in CD custody must, if capable, sign an informed consent participation agreement regardless of the level of their participation if they are at all involved with the research project. Among the study participation parameters, CD children must understand their ability to opt out after they have begun participation if they initially consent to participating. They must understand that participation is not compulsory and that making a decision not to participate will not be held against them. Guardians (i.e. foster parent, prospective adoptive parent, Social Service Worker, etc…) must also sign an informed consent form.

b. The Regional Administrator must prepare, in writing, a regional consent recommendation to submit to Central Office **if** the request to conduct research is received in the circuit.

c. The Regional Administrator must forward completed application, related documents, and regional consent recommendation to the CD Central Office for approval consideration **if** the request to conduct research is received in the circuit.

d. The committee (appointed by the Division Director) from Central Office will review the proposal and consider:

- Whether the entity completed the application and submitted relevant materials according to guidelines established by the CD.

- Whether the Regional Administrator sanctions the proposed research (evidenced by administrator's written consent recommendation if request came through the circuit office or by verbal consent if request was initiated in Central Office).

- Whether the research proposal is a bona fide request. Defined in Missouri Statute, 210.150.2 (13), a bona fide request is from any person who is a tenure-track or full-time research faculty member at an accredited institution of higher education engaged in scholarly research, with the permission of the director.

- Whether the research is being conducted for bona fide purposes and has the potential to advance child welfare practice in Missouri.

- Whether the research involves the use of Protected Health Information (PHI), i.e. Social Security Number (SSN), Departmental Client Number (DCN), Date of Birth (DOB), or client name.

3.1.1.1 When PHI is involved the research proposal must:

- Outline a viable plan to secure signed authorizations* from the study participants (inclusive of family members) and/or guardians or legal custodians as applicable **or**

- Outline a viable plan to ensure de-identification (anything, including DOBs, SSNs and case DCNs, that can be tied back to an individual to identify that individual with personal health information) of PHI associated to study participants.

- *It is preferable that the Department's "Authorization for Disclosure of Health Information" form (http://dssweb/dpl/adman/POLICIES/5-103ex2.pdf) be used where authorizations are required. Otherwise, it

must be ascertained that forms supplied by a researcher are "Privacy Rule"-compliant.

Note: It is permissible under the Privacy Rule that valid authorizations be combined with informed consents (if the authorization is valid and the consent adequately informs what a participant can expect from being involved).

e. The Division Director (or designee) will approve (or reject) the research proposal based on the recommendations of the committee members and will forward any approved proposal involving the use of PHI to the Divisional Privacy Officer for further review.

f. The Division Privacy Officer will review the request to determine whether the matter of client PHI disclosure is adequately addressed in the proposal.

g. The Divisional Privacy Officer will relate a position to the Division Director (or designee) whether the matter of PHI release is satisfactorily addressed and may submit the proposal to the Department Privacy Review Board if the proposal requires consideration of an 'authorization to disclose' waiver. The DSS Privacy Review Board is comprised of the DSS Privacy Officer, divisional privacy officers under the covered entity (DSS), and one qualified individual appointed by the DSS Director. The DSS Privacy Officer is the chairman of the DSS Privacy Review Board.

h. The Department Privacy Review Board will review the request and determine whether a waiver of the required authorization will be granted. The Divisional Privacy Officer will, in turn, notify the Division Director (or designee) as to whether the Division may proceed (and under what considerations if applicable) where PHI release is an issue. Waiver by the Board of the individual authorization required by Health Insurance Portability and Accountability Act (HIPAA) will be done in compliance with the provisions in CFR 164.512(i).

i. The committee will inform the requestor, in writing, of the decision.

j. The requestor is required to allow the Children's Division Director (or designee) to review the research findings before publication.

k. The requestor is required to send the Children's Division a copy of final product.

l. The Division Director shall designate a person in Central Office to monitor research activities for adherence to the agreed upon implementation terms in accordance with standards set forth by the Division Director (or designee). The person/s chosen to monitor such approved research requests shall keep

a record of all research activities. At least annually, the person/s chosen to monitor approved requests will conduct a review of research involving program participants to assess areas of overall risk to the Children's Division (in accordance with COA standard G2.5.02).

3.1.2 When Clinical Drug Studies Involving Human Subjects are Being Proposed

All of the above procedures apply to clinical drug studies involving human subjects. In addition to adhering to the above procedures, when clinical drug trials are being conducted on human subjects, the research entity must appoint an independent advocate for the child.

3.1.3 Request for Data Procedures

CD staff members are to follow procedures when request for data involves disclosure of client PHI, i.e. social security number (SSN), Departmental Client Number (DCN), Date of Birth (DOB), or client name. There is no need to obtain authorization to release data when no PHI is being requested. The Health Insurance Portability and Accountability Act (HIPAA) must be considered before data requests are approved. All data transfers will be done in compliance with the Information Security Management policy, 6-100 (http://dssweb/dpl/adman/POLICIES/6-100.pdf).

a. All requests for data must be sent to Central Office. The person designated by the Division Director to review all requests for data will complete a Data Transfer Request (http://dsswebapp/grd/DataTransfer/index.asp). The designee will consider:

   - Whether request for data is a bona fide request (from any person who is a tenure-track or full-time research faculty member at an accredited institution of higher education engaged in scholarly research, with the permission of the director).

   - Whether request for data was made for bona fide, ethical purposes and its intended use is likely to advance child welfare practice in Missouri.

b. If data to be transferred includes disclosure of client PHI, the designee will forward the Data Transfer Request electronically to the Divisional Privacy Officer. Under comments section of the Data Transfer Request Form, the designee shall describe what data is needed so that the Divisional Privacy Officer has a good understanding of the request.

c. Divisional Privacy Officer will receive the request electronically at which time he/she makes the decision whether to approve the request.

d. Divisional Privacy Officer signs off on the request which automatically generates an alert to the CD Security Officer.

e. The CD Security Officer signs off on the request and it automatically goes to Information Technology Services Division (ITSD).

f. Staff from ITSD sends a notification to everyone involved including the individual who initiated the request.

g. The Research and Evaluation Unit of DSS will determine whether to develop a file for tracking purposes.

3.1.4 CD Central Office Contact

Requests to conduct research and requests for agency data should be sent to Jim Harrison, Deputy Director, Children's Division, P. O. Box 88, Jefferson City, MO 65103.

MEMORANDA HISTORY: CD05-79